K120917
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510(k) Summary

AUG 2 2012

Trade Name:	Headway Duo Microcatheter
Generic Name:	Diagnostic Intravascular Catheter
Classification:	Class II, 21 CFR 870.1200, DQO
Submitted By:	MicroVention, Inc 1311 Valencia Avenue Tustin, California U.S.A.
Contact:	Naomi Gong
Date:	2012Mar23
Predicate Device:	Headway 17 Microcatheter (K083343)

Device Description:

The Headway Duo Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the microcatheter hub is used for the attachment of accessories.

Indication For Use:

The Headway Duo Microcatheter is intended for general intravascular use, including the peripheral and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as embolization materials.

The Headway Duo Microcatheter is intended for neurovascular use, for the infusion of diagnostic agents, such as contrast media, and therapeutic agents that have been cleared or approved for use the in neurovasculature and are compatible with the inner diameter of the Headway Duo Microcatheter.

Verification and Test Summary :

Bench Testing	**Result**
Surface and physical attributes	Pass
Distal tensile strength	Pass
Hub tensile strength	Pass
Hub test (ISO 594-2)	Pass
Leakage (liquid and air)	Pass
Static and dynamic burst pressure	Pass
Simulated use	Pass
Compatibility with devices	Pass

Flow rate	Pass
Kink resistance	Pass
Radio-detectability	Pass
Catheter flexural fatigue	Pass
Torque test	Pass
Particulate test	Pass
DMSO compatibility	Pass
Biocompatibility	**Result**
Cytotoxcitiy (ISO 10993-5) - MEM elution assay - Agarose overlay	Pass
Sensitization/Irritation (ISO 10993-10) - Guinea pig maximization sensitization - Intracutaneous reactivity	Pass
Hemocompatibility (ISO 10993-4) - Hemolysis - Prothrombin time assay - Complement activation C3a and SC5b-9 - 4 hour thromboresistance in dogs	Pass
Systemic Toxicity (ISO 10993-11) - Systemic toxicity - Rabbit pyrogen test	Pass

The Headway Duo has been verified to be compatible for use with embolization materials, such as occlusion coils, liquid embolic devices (such as Onyx® and Trufill® liquid embolic systems), and PVA particles.

Technological Comparison:

The Headway Duo utilizes the same fundamental technology, operating principle and intended use as the predicate device. The microcatheter length has been extended up to 157 and 168 cm.

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the Headway Duo Microcatheter when compared with the predicate device, Headway 17 Microcatheter (K083343).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Are packaged and sterilized using same material and processes.

In summary, the Headway Duo Microcatheter described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 2 2012

MicroVention, Inc
c/o Ms. Naomi Gong
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

Re: K120917
Trade/Device Name: Headway Duo Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: July 3, 2012
Received: July 5, 2012

Dear Ms. Gong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120917

Device Name: Headway Duo Microcatheter

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120917

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